EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **MDL NO. 2187**

THIS DOCUMENT RELATES TO

MARTINA WHEELER
Plaintiff,
v. **Case No. 2:12-cv-4580**

C.R. BARD, INC.,
Defendant.

RULE 26 EXPERT REPORT OF DANIEL S. ELLIOTT, M.D. FOR MARTINA WHEELER

I am providing my expert opinion regarding the Plaintiff, Martina Wheeler. The following represent my opinions, all held to a reasonable degree of medical probability and certainty. These opinions are based upon my background, training and experience as well as the totality of available data from all sources, which I have reviewed. I have filed my General Causation Expert report in MDL 2187 concerning Avaulta Plus and Avaulta Solo products. I rely upon my General Causation Expert report and incorporate that document by reference. I also rely upon the opinions of Bruce Rosenzweig, M.D., and Jerry Blavis, M.D., as set out in their General Causation Expert Reports also filed in this MDL. In so relying on Drs. Rosenzweig and Blavis, I have independently verified their opinions set out in their reports and conducted my own to verify their opinions. I reserve the right to supplement this report if new or supplemental information is provided at any point, and as I review other related documents.

I. QUALIFICATIONS

I am an Associate Professor of Urology, section of Female Urology and Reconstructive Surgery, at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. My current curriculum vita, attached hereto as Exhibit "A", more fully and accurately reflects my training, background, academic activity and publications. However, briefly, I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed one year of General Surgery and five years of Surgical Urology residency at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the

faculty at the Mayo Clinic, where I have spent the last fourteen years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published nearly 60 peer-reviewed articles and given over a 100 lectures nationally and internationally pertaining to urinary incontinence and pelvic organ prolapse. I have specifically authored two published scientific manuscripts dealing with polypropylene meshes in the animal model. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject and the first to perform and publish on the outpatient, non-mesh transobturator sling.

During my training, I was introduced to the use of synthetic midurethral slings for incontinence repair. I have used the Mentor OB/Tape products as well as mesh slings made by AMS and Coloplast. As of almost a year ago, I decided to no longer use meshes in my practice through the transvaginal route unless there is absolutely no other alternative. The reason that I made this decision is that my practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Bard. Neither I, nor my colleagues at Mayo, have ever used transvaginal POP kits as we felt that the risk to patients was too great. Having treated hundreds of patients with mesh-related complications (both SUI and POP), I feel that we made the right decision not to include them as part of our treatment regimen. I only use mesh for POP repair through robotic sacrocolpopexy as it is not a transvaginal surgery, uses much less mesh, and is associated with significantly less complications than transvaginal mesh prolapse repair.

I am a frequent invited national and international lecturer at medical and surgical conferences addressing stress urinary incontinence and pelvic organ prolapse, their evaluation, treatment, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

I am attaching my Curriculum Vitae (Exhibit "A"). I am also attaching a copy of my testimony for the last four years (Exhibit "B"). My reliance documents are listed on Exhibit "C".

II. MARTINA WHEELER MEDICAL RECORDS REVIEW AND CASE REPORT

At the time of her 2008 Avaulta and Align placement, Ms. Wheeler was a 50 year old woman who had two vaginal deliveries. Ms. Wheeler was referred to Dr. Marja Sprock, with a chief compliant of prolapse (rectocele and cystocele), uterus dropping, and partial stress urinary incontinence.[1]

Ms. Wheeler's medical/surgical history is positive for Osler Weber Rendu Syndrome, Gastroesophageal reflux disease (2003), Thyroid disorder/Hashimoto's (1990), Dysuria, anxiety, prolapse-utreovaginal, hypothyroidism, rhinoplasty, tubal ligation, right salpingooophorectomy

[1]See Marja Sprock Deposition testimony, Page 67 and 68, 86, and 87, September 10, 2014; also reference WUESH00008-10/ZUA00006-8.

for ectopic pregnancy, depression, bio-polar, fibroids[2] and hepatic steatosis. Ms. Wheeler is also a former smoker who had quit more than 20 years prior to her procedure.[3]

Ms. Wheeler presented to Dr. Marja Sprock initially on May 30, 2008 for pelvic organ prolapse.[4] On July 7, 2008, Dr. Marja Sprock implanted the Avaulta Solo (posterior), Avaulta Solo (anterior) and Align TOT devices[5] manufactured by C.R. Bard, Inc. The operative report states that Dr. Sprock performed (1) an anterior repair with polypropylene mesh; (2) posterior repair with polypropylene mesh; (3) transobturator tape insertion; and a (4) cystoscopy.[6] Dr. Sprock testified that Ms. Wheeler tolerated the procedure well and there were no complications.[7] This is consistent with the medical records. Ms. Wheeler was discharged home with a fully functioning cather in place.[8]

On July 22, 2008, Ms. Wheeler presented to Dr. Sprock's office for an unscheduled post-operative follow-up visit with complaints of "left leg pain and something yellowish that she has seen in her vagina when she started checking with the mirror".[9] Dr. Sprock testified that the "tissue can turn a little yellowish [. . .] it's part of the healing process."[10] This procedure was uncomplicated.

On August 26, 2008, Ms. Wheeler again presents to Dr. Sprock, with complaints of "pelvic pressure", "pain recturm", "nocturia from five to two times."[11] Upon examination, Dr. Sprock noticed an "anterior four millimeter [mesh] extrusion."[12] Dr. Sprock trimmed the extrusion and sutured the site closed.[13]

On Ms. Wheeler' September 23, 2008 (8 week) postoperative visit with Dr. Sprock, Dr. Sprock again noted vaginal mesh extrusion. At this time, Dr. Sprock recommended, "Pt desired reassurance. Aware of mucosa dehiscense, not bothering with intercourse, pt fine like it is." However, Ms. Wheeler's symptoms progressed and Ms. Wheeler returned to see Dr. Sprock on October 10, 2008. On this visit, Dr. Sprock noted "A mesh extrusion is noted." Again, Dr. Sprock elected to treat the mesh extrusion in the office with "Ant extrusion cut" and continued conservative therapy.

These treatment measures failed and Ms. Wheeler sought care Dr. Murrary Dweck on September 5, 2012. On his evaluation he noted that Ms. Wheeler "Always has pain with intercourse since surgery." Also, he noted that "… over last 2 months has had swelling and pelvic pain and back pain." Ms. Wheeler also continued to have a bloody vaginal discharge

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[2] Deposition of Ralph Zipper, September 3, 2014, at p. 109.
[3] Marja Sprock Deposition testimony, Page 87, September 10, 2014.
[4] Marja Sprock Deposition testimony, Page 67, September 10, 2014.
[5] WUESH00012/PSR00052, See also BHA00107-108/WUESH00020-22/ZUA00003-5; see also Deposition testimony of Marja Sprock; Deposition testimony of Ralph Zipper, September 3, 2014, pages 33-35.
[6] BHA00107-108/WUESH00020-22/ZUA00003-5
[7] Marja Sprock Deposition testimony, pgs. 96-97, and pg. 100-101 September 10, 2014.
[8] Marja Sprock Deposition testimony, pg. 101, September 10, 2014.
[9] ZUA00032/PSR00012; Marja Sprock Deposition testimony, Page 102, September 10, 2014.
[10] Marja Sprock Deposition testimony, Page 103, September 10, 2014.
[11] Marja Sprock Deposition testimony, Page 103-104, September 10, 2014.
[12] Marja Sprock Deposition testimony, Page 104, September 10, 2014.
[13] Marja Sprock Deposition testimony, Page 104, September 10, 2014.

following sexual activity ("Also has post coital bleeding."). Due to the complex nature of Ms. Wheeler's problems, Dr. Dweck referred Ms. Wheeler back to Dr. Sprock.

On September 18, 2012 Ms. Wheeler returned to see Dr. Sprock. On this visit Dr. Sprock noted "... they [Palm Bay Health Department] told her that the mesh was deteriorating" and that Ms. Wheeler "Went to health department because of [vaginal] bleeding." Dr. Sprock also noted that Ms. Wheeler was "Mostly worried about carcinoma, mesh eating her" and "Having some [vaginal] discomfort," and that her "Husband stated he feels the mesh during intercourse." According to Dr. Sprock Ms. Wheeler's vaginal pain began "Shortly after surgery felt the mesh-6 months after surgery had bleeding, went away, through years had some bleeding." Dr. Sprock recorded that Ms. Wheeler was experiencing "... [vaginal] bleeding every day." Because of the vaginal pain according to Dr. Sprock's notes, Ms. Wheeler was "Sexually active, not often because of her pain…" Ms. Wheeler described her vaginal pain as "Sharp, swelling like toothache." On the Visual Analog Severity scale Dr. Sprock graded her daily vaginal and pelvic pain as 4 (out of ten). However, during intercourse, Dr. Sprock recorded Ms. Wheeler's pain as severe, "level = 8-10 [out of ten]." Also, Dr. Sprock noted that Ms. Wheeler "Has pain during urination." This pain began "Onset of pain 3-4 years [ago]." On physical exam, Dr. Sprock discovered a bloody vaginal discharge, and mesh extrusion located in the "middle split open, some mesh visible." Dr. Sprock discussed conservative treatment with vaginal estrogen.

Ms. Wheeler then sought a second opinion from Dr. Ralph Zipper. On August 7, 2013, Ms. Wheeler was seen by Dr. Ralph Zipper with complaints of urgency of urination, frequency, nocturia, dysuria, pain with intercourse, and "feeling like she wasn't emptying her bladder".[14] Examination of vagina revealed banding consistent with mesh arm @ -2 cm of the anterior compartment, tender to palpation and mesh extrusion.[15] Dr. Zipper attributed the banding to be the cause of her complaints.[16] Dr. Zipper offered excision of the mesh with reapproximation of mucosa and cutting of mesh, which may be contributing to dyspareunia.[17] Dr. Zipper provided samples of Myrberiq. Ms. Wheeler was counseled regarding her surgical options and surgery for a wide excision of the mesh was scheduled.

On September 16, 2013, excision of the Avaulta and an anterior colporrhapy was performed by Dr. Zipper.[18] Following discussion and informed consent Dr. Zipper returned Ms. Wheeler to the operating room on September 16, 2013. The indications for this repeat surgery were "Symptomatic mesh extrusion," "Pelvic pain," and "Dyspareunia." Dr. Zipper excised a "1 x 2 cm anterior compartment mesh extrusion." Also during surgery noted that the Avaulta was "Rolled-up mesh." [19] During the course of the procedure and excision of the mesh, Dr. Zipper noted that the anterior vaginal prolapse had recurred necessitating additional POP surgery to repair this recurrent prolapse. Therefore, he performed a traditional anterior colporrhaphy with sutures." The procedure was uncomplicated and Ms. Wheeler was discharged from the hospital without complications.

[14] ZUA00033-34; See also Deposition of Ralph Zipper, September 3, 2014, at pgs. 41-42.
[15] Id. See also Deposition of Ralph Zipper, September 3, 2014, at pg. 45.
[16] Deposition of Ralph Zipper, September 3, 2014, at p. 45-46.
[17] Id.
[18] Deposition of Ralph Zipper, September 3, 2014, at page 17, 20 and 106.
[19] Deposition of Ralph Zipper, September 3, 2014, at 53.

After the initial mesh implant, Ms. Wheeler's life has changed. She has experienced pain in her vagina, colon, and side.[20] Her relationship with her husband has suffered and she is not able to engage in sexually activity post-implant as frequently as pre-implant.[21] She cannot enjoy riding a bike, due to the pain, and has difficulty at work.[22]

Currently, Ms. Wheeler is only rarely sexually active. When she attempts intercourse it is so painful that she is forced to stop. She grades her pain level during sex as a 8 on the VAS. On a daily basis she has near constant pelvic pain, fullness and pressure. On the VAS she scores the pain at a 6-7. The impact upon her quality of life has been tremendous because now she cannot engage in any meaningful sexual activity and has lost that intimacy. The pain level has created a significant emotional burden on her. Also, due to the pain level she can no longer be as active as she once was and is no longer able to walk for long distances or stand for any prolonged period of time. There are no non-mesh related post-implant conditions that would have caused Ms. Wheeler's VAS pain scale to increase from a VAS score of 0 pre-mesh implant, to a VAS of 8, post-implant.

On October 4, 2014 in Nashville, Tennessee, I personally examined Ms. Wheeler. The pertinent components of my examination demonstrated the following:

- Neurologic without gross deficit
- Abdomen without masses
- Vagina/Urinary system:

The urethra was in normal position and configuration. The vagina was well estrogenized. The vaginal lumen length is within normal range. Palpation of the skin at the introitus was nontender. On the VAS, Ms. Wheeler rated the pain at a 0.

Deeper light palpation laterally along Levator ani muscles causes significant tenderness bilaterally. The intensity of the pain levels was equal on both sides. With palpation Ms. Wheeler and was unable to hold still. On the VAS, Ms. Wheeler rated the pain at a 6. Palpation along the entire anterior vaginal wall and urethra was tender to light touch. On the VAS, Ms. Wheeler rated the pain at a 3-4. Palpation along the entire posterior vaginal wall was nontender to palpation. On the VAS, Ms. Wheeler rated the pain at a 0.

At the anterior mid-portion of the vagina, just deep to the descending pubic rami was extremely painful to Ms. Boylard (VAS = 8-9) with the left side being greater than the right side. There was no visible evidence of mesh extrusion, however, the mesh arms were palpable bilaterally in this region. Specifically when the mesh arms themselves were palpated it cause severe pain with the left being greater than the right. On the VAS, Ms. Wheeler rated the pain at a 7-8. Adduction of the thighs bilaterally also elicited significant pain (VAS = 5). External palpation over the obturator foremen caused bilateral pain. On the VAS, Ms. Wheeler rated the pain at a 2-3. These findings are consistent with severe irritation in the region of the obturator foramen. Palpation over the buttock in the region of the mesh arms was painful on the right but not on the left. On the VAS, Ms. Wheeler rated the pain at a 3-4.

[20] See e.g. Martina Wheeler Deposition testimony, pgs. 239-240, June 4, 2014.
[21] See e.g. Martina Wheeler Deposition testimony, pg. 240-242, June 4, 2014.
[22] See e.g. Martina Wheeler Deposition testimony, pg. 257-259, June 4, 2014.

The anterior, posterior and apical vaginal walls were well supported at rest and with Valsalva. She had mild urethral hypermobility with no SUI noted, however, her bladder was empty at the time of examination.

Based upon my medical education, my review of the currently available medical literature pertaining to Ms. Wheeler, and my physical examination of Ms. Wheeler, with a high degree of medical certainty, I have come to the following medical diagnoses:

1. Ms. Wheeler has severe pelvic pain consistent with pelvic floor myalgia

2. Ms. Wheeler has severe vaginal pain resulting in severe dyspareunia.

3. As a result of the implantation of Avaulta and the subsequent reaction, Ms. Wheeler's vagina has severe pain.

4. Through no fault of the implanting surgeon, the resultant reaction from Avaulta has caused severe compromise in Ms. Wheeler's quality of life.

Based upon my medical education, my experience, my review of the currently available medical literature pertaining to Ms. Wheeler, and my physical examination of Ms. Wheeler, with a high degree of medical certainty, I have come to the following conclusions regarding Ms. Wheeler's prognosis and chance for recovery:

1. Pelvic Pain: Prognosis is poor. It is highly unlikely, even with aggressive surgery, physical therapy and biofeedback, for Ms. Wheeler to have complete resolution of the pelvic pain.

2. Pelvic Floor Myalgia: Prognosis is poor. It is highly unlikely, even with aggressive physical therapy, biofeedback and pelvic floor retraining, for Ms. Wheeler to have complete resolution of the pelvic floor dysfunction.

3. Urinary Urge Incontinence: With proper evaluation and surgical treatment it is possible for Ms. Wheeler to regain adequate control of her urine. However, repeat surgical intervention will be more challenging and the likelihood of success will be less than first time surgery.

4. Dyspareunia: Prognosis is poor. It is highly unlikely, even with aggressive surgery, physical therapy, biofeedback and pelvic floor retraining, for Ms. Wheeler to have complete resolution of her sexual dysfunction.

5. As a consequence, the lack of physical intimacy has already cost Ms. Wheeler a major component to her quality of life. Without a major reduction in her symptoms she is unlikely to ever regain the benefit of physical intimacy again in her life. The long-term impact on her quality of life is difficult to accurately ascertain, however, many studies

have shown the long-term negative impact leading to feelings of isolation, loneliness, depression and suicide.

- Sepulcri Rde et al: Depressive symptoms, anxiety, and quality of life in women with pelvic endometriosis. Eur J Obstet Gynecol Reprod Biol. 2009 Jan;142(1):53-6.
- Mathias SD, Kupperman M et al: Chronic pelvic pain: prevalence, health-related quality of life, and economic correlates. Obstet Gynecol. 1996 Mar;87(3):321-7.

III. CASE SPECIFIC OPINIONS FOR MARTINA WHEELER

My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of these opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report. The materials I have reviewed and relied upon to form my opinions for this report are listed in Exhibit "C" to this report.

I have been asked to review the pertinent medical records (~1925 pages) pertaining to the care of Ms. Wheeler, to perform an independent medical exam of her and to provide this written report regarding my opinions of her care, surgery, and treatment. Also, I have been asked to provide a written diagnosis and prognosis, and have done the same in my report, attached hereto, following my review of her records and examination of Ms. Wheeler.

Determining the cause of a specific injury is a two step process. First, one must "rule in" potential causes. Second, through a process of elimination, "rule out" the least likely causes until only the most likely causes remain under consideration. This process is known as differential diagnosing or differential etiology. It is a well-established and universally accepted methodology for determining the cause of injuries and illnesses by physicians throughout the United States. When determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Based upon my review of Ms. Wheeler's medical records, my experience and education, review of the available medical literature and examination of Ms. Wheeler, I currently hold the

following opinions to a reasonable degree of medical certainty. I reserve the right to supplement and revise my opinions regarding Ms. Wheeler if further information becomes available.

1. Ms. Wheeler was not able to make a fully informed medical decision regarding the implantation of Avaulta mesh because Bard failed to fully disclose the risks, complications (both early and late) in Avaulta's Instruction for Use.

2. Ms. Wheeler's implanting surgeon was not able to provide the necessary and required information to Ms. Wheeler for an informed consent because Bard failed to fully reveal such information and failed to fully evaluate said information prior to launch.

3. Ms. Wheeler has developed complications as described above as a result of the Avaulta being implanted in her body.

4. As a result of these complications from the Avaulta device, Ms. Wheeler has suffered damages and will continue to suffer future damages.

5. I have personally reviewed Ms. Wheeler's medical bills as a result of her treatment and surgeries related to the implantation of Avaulta device and its complications and I believe they are reasonable and necessary.

6. These complications have taken a significant impact on Ms. Wheeler's quality of life. Prior to the surgery, she was healthy, physically and sexually active individual. Now Ms. Wheeler has been forced to dramatically reduce these activities due to her poorly controlled pelvic and vaginal pain. Ms. Wheeler can no longer enjoy a normal sexual life because of the severity of her vaginal and pelvic pain.

Ms. Wheeler suffered injuries as a direct result of the implantation of the Avaulta devices. As stated in my General Expert Liability Report, the polypropylene mesh utilized in the Avaulta product was not intended for human use. Bard did not convey this information to Ms. Wheeler[23]or Dr. Sprock.[24] In fact, Dr. Sprock testified that had she known that the material used in the Avaulta product was not for human use, she "would not have used it."[25]

Set out in my general causation expert report, several characteristics of the Marlex polypropylene mesh render it inherently unsafe for use in Ms. Wheeler. First, Bard utilizes non-medical grade polypropylene, the supplier of which has forbidden its use in humans because of

[23] Deposition of Martina Wheeler, June 4, 2014, pages 297-299.
[24] Deposition of Dr. Marja Sprock, September 10, 2014, pgs. 78-79.

[25] Deposition of Dr. Marja Sprock, September 10, 2014, pg. 82.

its known degradation characteristics. Second, the mesh should have large pores at least 2 mm in its shortest diagonal. Third, it should be lightweight, i.e. less than less than 35 g/m^2 dense. Fourth, it should not be inserted blindly with metal trocars. Fifth, it should not have its flat mesh arms pulled through narrower, rounded trocar wounds. These characteristics, in my opinion to a reasonable degree of medical certainty and probability, caused Ms. Wheeler to suffer her permanent injuries: pain, loss of enjoyment of hobbies such as riding a bike,[26] and dyspareunia, and are a direct result of the C.R. Bard, Inc. products implanted into her body.

It is my opinion to a reasonable degree of medical certainty that Ms. Wheeler's post-implant medical treatment results from her complications stemming from the Bard implant. Following the implant, Ms. Wheeler mesh extrusion and pain during intercourse. I have reviewed medical records reflecting that Ms. Wheeler suffered from multiple mesh extrusions as well as scarring and banding. It is my opinion, to a reasonable degree of medical certainty and probability, that no other causes for her symptoms exists other than the mesh as she has not developed any medical conditions or life events that would cause her current problems.

Further, based on my background, education, training, and experience, it is my opinion that Dr. Sprock's treatment of Ms. Wheeler met the standard of care, when implanting and excising the mesh. It is also my opinion that the care and treatment by Dr. Zipper to remove mesh also met the standard of care. Both the implant and explant procedures were performed within the standard of care, with no evidence of surgeon error or deviation from the requisite procedural steps or the standard of care. Furthermore, none of the historical or medical conditions she had prior to 2008, would cause her current conditions.

As set forth in my general report, safer alternative designs to the mesh were available. And so, it is my opinion to a reasonable degree of medical certainty and probability that alternative treatments were available to treat Ms. Wheeler.

Also, as set out in my general report, C.R. Bard, Inc., failed to provide adequate warnings[27] of the defects in the design of the mesh and system of implantation, as well as the adverse events resulting from those defects to Ms. Wheeler's physicians

Since Bard knew of these risks they should have been clearly placed on the IFU so that not only Ms. Wheeler implanting surgeon would be fully informed of the risks but also Ms. Wheeler could have been completely informed of the risk on her informed consent. The following lists the risks that were known but Ms. Wheeler was not informed of on her informed consent:

1. Inadequate Pre-launch Testing and durability studies.
2. Ineffective procedure puts women through surgery with unacceptably high failure rate.
3. Dangerous Procedure with incomplete IFU specifications regarding tensioning and appropriate use of trocars thereby leading to complications and failure.
4. Inadequate data to support use of Avaulta in the Pelvic Floor.

[26] Deposition of Martina Wheeler.
[27] See e.g. Deposition of Ralph Zipper, September 3, 2014, pages 174-175.

5. That the Avaulta devices can cause chronic, permanent debilitating pain.
6. Incomplete warnings regarding increased inflammatory tissue response to Avaulta.
7. Incomplete warnings regarding the inherent nature of the Avaulta mesh a predictable increased immune response to the presence of the mesh is set off.
8. Incomplete warnings regarding the increased inflammatory and immune response causes increased risk for product breakdown and subsequent product failure.
9. Incomplete warning and pre-launch evaluations regarding the host's acute inflammatory response to Avaulta.
10. That Avaulta mesh can cause a lifelong risk of vaginal extrusion.
11. That Avaulta could cause a lifelong risk of pelvic organ erosion.
12. That erosions and extrusions can be severe and incurable. Incomplete warning and pre-launch evaluations regarding the host's chronic inflammatory response to Avaulta.
13. Insufficient evaluation regarding implantation of Avaulta into the contaminated field of the vagina.
14. Insufficient evaluation regarding Avaulta product degradation/product Failure due to product degradation
15. Insufficient evaluation and warnings regarding Avaulta -related complications not seen in traditional repair.
16. That Bard knew of data that the risk of vaginal scarring was greater than it disclosed in its IFU.
17. Avaulta's pelvic mesh products products are defective due to Bard's failure adequately test the product prior to launch, failure to appropriately warn patients and health care providers of range, severity and magnitude of risks and complications including, but not limited to, the following:

    a. The products' frequent tendencies to degrade, fragment, and elongate;
    b. The risk of the mesh causing a host versus implant immune response causing a chronic inflammation reaction resulting in pain and product failure;
    c. The risk of chronic infections resulting from the products;
    d. Risk of chronic foreign body reaction due to the presence of the product;
    e. The risk of permanent vaginal or pelvic scarring as a result of the products interaction with the host;

f. The risk of permanent vaginal shorting as a result of the products;

g. The risk of intractable pelvic, vaginal, urethral, and systemic pain and resulting from the products interaction with the body;

h. The need for corrective or revision surgery to revise or attempt to remove the products;

i. The severity of complications such as pelvic pain, vaginal pain, dyspareunia, overactive bladder, voiding pain that could arise as a result of implantation of the products;

j. That Avaulta devices could cause permanent dyspareunia

k. That Avaulta devices could cause permanent pelvic pain

l. That the Avaulta device could cause narrowing of the vaginal vault.

m. The frequency of complications that could arise as a result of implantation of the products;

n. The pre-existing knowledge of the severity and frequency of complications resulting from the products implantation;

o. Folding of the product inside the body;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible available alternatives;

q. Treatment of pelvic organ prolapse and stress urinary incontinence with the products exposes patients to greater risk than feasible available alternatives;

r. Treatment of pelvic organ prolapse and stress urinary incontinence with the products makes future surgical repair more difficult than feasible available alternatives;

s. The use of the products puts the patients at greater risk of requiring additional surgery;

t. The removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

u. Complete removal of the products is most likely not possible and may not result in resolution of the complications, including pain; and recurrent urinary leakage and pelvic organ prolapse.

18. Insufficient evaluation regarding and warning regarding the pullout forces of the Avaulta.

19. Insufficient evaluation regarding and warning regarding the pullout forces of Avaulta if the mesh were to be adjusted (pulled back and forth) during the mesh tensioning portion of the procedure.

20. Insufficient evaluation regarding and warning regarding the mesh sling anchoring configuration and "rolling potential" once in place in the body and rectus abdominis muscle and fascia.

21. Insufficient evaluation regarding, warning and IFU guidance for Avaulta placement in morbidly obese patients.

Ms. Wheeler did not receive information about the above risks because Bard did not disclose them fully in its IFU and surgeons, including the implanting surgeon in Ms. Wheeler's case, were not made aware of them. This is true despite information readily available to Bard about these risks, which predate the launch of the device. Because of this, Ms. Wheeler's implanting surgeon could not pass this information on to her and properly consent her about the risks associated with the Avaulta device. Ms. Wheeler was unable to make a fully informed decision about having the cook device implanted. As a result, to a reasonable degree of medical certainty, Ms. Wheeler suffered injuries that were not disclosed to her by Bard and the inadequate disclosure of these risks were a substantial factor and/or cause of Ms. Wheeler's injuries.

I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.

Dated this 8th day of October, 2014.

Daniel S. Elliott

EXHIBIT A

Curriculum Vitae and Bibliography
Daniel S. Elliott, MD

Present Academic Rank and Position

Consultant - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2003 - Present
Associate Professor of Urology - Mayo Clinic College of Medicine	01/2013 - Present

Education

Biola University - BS, Biological Science	1988
School of Medicine, Loma Linda University - MD	1993
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Internship, General Surgery	1993 - 1994
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Resident, Urologic Surgery	1994 - 1999
Baylor College of Medicine - Fellow, Neurourology, Urodynamics and Voiding Dysfunction	1999 - 2000

Additional Education

UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2004
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2005
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2006
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2007
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2008
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2009
Coloplast Surgical Training - Male Sling New York, New York	06/2009
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2010
UCLA State-of-the-Art Urology UCLA Marina del Rey, California	03/2011

UCLA State-of-the-Art Urology 03/2012
UCLA
Marina del Rey, California

Comprehensive Review Course in Female Pelvic Medicine and Reconstructive Surgery 04/2013
Dallas, Texas

AUA Hands-On Ultrasound Training Course 10/2014
Rochester, Minnesota

Certifications

Board Certifications

American Board of Urology

Urology 2002 - Present

Urology/Female Pelvic Medicine and Reconstructive Surgery 08/2013 - Present

Honors/Awards

AUA Resident Award - John D. Silbar North Central Section 10/1998

Urology Grant Recipient - Pfizer Scholars 01/1999

DeWeerd Travel Award Recipient 06/1999

Annual Audio-Visual Award - AUA - American Urological Association, Washington, District of Columbia 05/2011

Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters - Third Prize - Landon Trost, Daniel Elliott

Best Reviewer in 2011 Award - Urodynamics/Incontinence/Female Urology/Neurourology - The Journal of Urology 05/2012

Best Reviewer in 2012 Award - Urodynamics/Incontinence/Female Urology/Neurourology - The Journal of Urology 05/2013

Annual Audio-Visual Award - AUA - American Urological Association, San Diego, California 05/2013

Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement - First Honorable Mention - Landon Trost, Daniel Elliott

Previous Professional Positions and Major Appointments

Senior Associate Consultant - Department of Urology, Mayo Clinic, Rochester, Minnesota 07/2000 - 06/2003

Assistant Professor of Urology - Mayo Clinic College of Medicine 04/2002 - 12/2012

Professional & Community Memberships, Societies and Services

Professional Memberships & Services

American Medical Association

Member 1991 - 2001

American Association of Clinical Urologists

Member 1998 - 2005

American Urological Association

Member 2000 - Present

International Continence Society

Member	2001 - Present
Society for Urodynamics & Female Urology	
Member	2002 - Present
Education Committee	
Committee Member	08/2014 - Present
Minnesota Medical Association	
Member	2002 - Present
Zumbro Valley Medical Society	
Member	2002 - Present
Olmsted County Medical Association	
Member	2002 - Present
International Urogynecologic Society	
Member	2003 - Present
Society of Urologic Prosthetic Surgeons	
Member	2005 - Present
Society of Laparoendoscopic Surgeons	
Member	2005 - Present
Minimally Invasive Robotic Association	
Member	2005 - Present
Minnesota Urological Society	
Member	2006 - Present
European Association of Urology	
International Member	03/2013 - Present
Section of Genitourinary Reconstructive Surgeons	
International Member	03/2013 - Present
Committee Member	04/2014 - Present
Section of Female and Functional Urology	
International Member	04/2013 - Present
International Urogynecologic Association	
Member	05/2013 - Present
International Pelvic Pain Society	
Member	05/2014 - Present

Journal Responsibilities

Journal Editorial Responsibilities

Journal of Robotic Surgery	
Consulting Editor	
Journal of Gynecology and Obstetrics	
Editorial Board Member	

Journal Other Responsibilities

Mayo Clinic Proceedings	
Reviewer	
Neurourology and Urodynamics	

Reviewer

The Journal of Urology

Reviewer

Journal of Investigative Urology

Reviewer

Nature Clinical Practice Urology

Reviewer

Mayo Clinic Health Letter

Reviewer

Archives of Gynecology and Obstetrics

Reviewer

Journal of Endourology

Reviewer

European Journal of Obstetrics & Gynecology and Reproductive Biology

Reviewer

Cleveland Clinic Journal of Medicine

Reviewer

Contemporary Clinical Trials

Reviewer

International Urogynecology Journal

Reviewer

Canadian Urological Association Journal

Reviewer, Canada

Urologia Internationalis

Reviewer

Educational Activities

Teaching Intramural

Prostate Pathology 03/2005
Mayo Medical School
Rochester, Minnesota

Institutional/Departmental Administrative Responsibilities, Committee Memberships and Other Activities

Mayo Clinic in Rochester

Department of Urology

Education Committee

Committee Member 02/2003 - 11/2008

Committee Member 10/2013 - Present

Presentations Extramural

National/International

Invited

Robotic Urogynecologic Surgery 03/2008
3rd Annual World Robotic Urology Symposium
Orlando, Florida

Robotic Sacrocolpopexy 01/2009
2009 International Robotic Urology Symposium (IRUS), Henry Ford Health System
Las Vegas, Nevada

Current Status Robotic GYN Surgery 01/2010
2010 International Robotic Urology Symposium (IRUS), Henry Ford Health System
Las Vegas, Nevada

Robotic Sacrocolpopexy 09/2010
28th World Congress on Endourology and SWL
Chicago, Illinois

Female Urology 09/2010
28th World Congress on Endourology and SWL
Chicago, Illinois

Optimizing Quality of Life With Regard to Urologic Function After Sacrectomy 01/2013
The 4th Annual Sacral Tumor Study Group Conference, Massachusetts General Hospital
Boston, Massachusetts

Treatment of Bladder and Urethral Mesh Erosion: Remove and Reconstruct 02/2015
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
Scottsdale, Arizona

Oral

Long Term Follow-Up of Endoscopically Treated Upper Tract Transitional Cell Carcinoma 04/1995
American Urological Association Annual Meeting
Las Vegas, Nevada

Transabdominal Enzymatic Ablation of the Prostate in the Canine Model: Evaluation for Use for the Treatment of Outflow Obstruction Due to Benign Prostatic Hyperplasia 05/1996
Urodynamics Subsection Meeting, American Urological Association
Orlando, Florida

Long Term Analysis of 323 AMS 800 Artificial Urinary Sphincters 05/1996
Urodynamics Subsection Meeting, American Urological Association
Orlando, Florida

Analysis of Functional Durability of AMS 800 Artificial Urinary Sphincter: The Mayo Clinic Results 04/1997
American Urological Association Annual Meeting
New Orleans, Louisiana

Long Term Follow-Up Primary Realignment of Urethral Disruption Following Pelvic Fracture 04/1997
American Urological Association Annual Meeting
New Orleans, Louisiana

Does Reoperation on an Artificial Urinary Sphincter Increase the Likelihood for Further Reoperations for Mechanical or Nonmechanical Failure? American Urological Association Annual Meeting San Diego, California	06/1998
Is Nephroureterectomy Necessary in All Cases of Upper Tract Transitional Cell Carcinoma? Long Term Results of Conservative Endourology Management of Upper Tract Transitional Cell Carcinoma in Individuals with Normal Contralateral Kidneys American Urological Association Annual Meeting Dallas, Texas	05/1999
Durability of Cadaveric Pubovaginal Sling American Urological Association Annual Meeting Anaheim, California	06/2001
Does the Addition of Antibiotic Prophylaxis to CIC Alter the Incidence of UTI? American Urological Association Annual Meeting Orlando, Florida	06/2002
Surgical Approach for Placement of SPARC Suburethral Sling North Central Section, American Urological Association Chicago, Illinois	10/2002
SPARC suburethral sling: technique and results (Video Presentation) Western Section, American Urological Association Kauai, Hawaii	11/2002
Robotic laparoscopic sacrocolpopexy: new surgical technique for the treatment of vaginal vault prolapse (Video Presentation) American Urological Association Chicago, Illinois	04/2003
Colloquium-ICS/IUGA 2004 Paris, France	08/2004
Robotic-Assisted Laparoscopic Management of Vaginal Vault Prolapse Minimally Invasive Robotics Association Innsbruck, Austria	12/2005
Advancement in Salvage Procedure Following Failed Artificial Urinary Sphincter: Tandem Transcorporal Artificial Urinary Sphincter Cuff Technique (Video Presentation) American Urological Association Atlanta, Georgia	05/2006
Tandem Transcorporal Artificial Urinary Sphincter Cuff Salvage Technique Following Previous Cuff Erosion and Infection: Surgical Description and Outcome Western Section, American Urological Association Maui, Hawaii	10/2006
Assessment of Durability of Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Minimally Invasive Robotics Association New York, New York	01/2007
Minimally Invasive Advances: Stress Incontinence Mayo Clinic Rochester, Department of Urology Kohala Coast, Hawaii	02/2007

Treatment Options for the Failed Sling Mayo Clinic Rochester, Department of Urology Kohala Coast, Hawaii	02/2007
American Urological Association Annual Meeting Anaheim, California	05/2007
Robotics use in Gynecology: the Mayo Clinic experience Robotic Surgery: Facts or Fiction? Milano, Italy	06/2007
Indication and Management of Artificial Urinary Sphincter 7th Osijek Urological Days Osijek, Croatia	10/2007
Robotics Use in Gyenocology 7th Osijek Urological Days Osijek, Croatia	10/2007
Robotic Urogynecologic Surgery 3rd Annual World Robotic Urlogy Symposium Orlando, Florida	03/2008
Latest Advances and Treatment of Complications in Minimally Invasive Treatments for Stress Incontinence American Urological Association (AUA) Orlando, Florida	05/2008
Severe, recurrent bladder neck contracture after prostatectomy: Salvage with urethral wall stent(Video and Poster Presentation) American Urological Association (AUA) Orlando, Florida	05/2008
Surgical Advances of Stress Urinary Incontinence Indian American Urological Association (IAUA) Orlando, Florida	05/2008
Robotic Sacrocolpopexy International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2009
Overactive Bladder: Current Concepts of Management Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
Minimally Invasive Advances: Stress Incontinence Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
Management of Complications Following Anti-Incontinence Procedures Mayo Clinic, Department of Urology, Rochester Meeting Kona, Hawaii	02/2009
American Urological Association (AUA) Chicago, Illinois	04/2009
Robotic repair for vaginal prolapse has significant benefits North Central Section of the AUA - 83rd Annual Meeting Scottsdale, Arizona	11/2009

Current Status Robotic GYN Surgery International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2010
Robotics for Female Pelvic Reconstruction: Who, When and What? American Urological Association (AUA) San Francisco, California	05/2010
Results of Urethral Wrap As Salvage Treatment Option Following Multiple Failed Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	09/2010
Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters Audio-Visual American Urological Association (AUA) Washington, District of Columbia	05/2011
Long-Term Results of Small Intestinal Submucosa at Artificial Urinary Sphincter Placement for Management of Persistent / Recurrent Incontinence Following Multiple Sphincter Failures and Erosions North Central Section of the AUA Rancho Mirage, California	10/2011
OAB Current Concepts and Management Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Treatment and Evaluation of the Complicated Artificial Urinary Sphincter Patient Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Transvaginal Mesh Kits Complications and Alternatives Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Vaginal Mesh for POP: what's the data show? American Urological Association (AUA) Atlanta, Georgia	05/2012
How do different centres perform Robot-assisted-Sacrocolpopexy? 4th Annual Society of European Robotic Gynecological Surgery (SERGS) Marseille, France	06/2012
Comparative Surgical Complications of the Robotic Sacrocolpopexy for Pelvic Organ Prolapse vs. Traditional Transabdominal Sacrocolpopexy European Robotic Urology Symposium (ERUS) London, United Kingdom	09/2012
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013

Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas American Urological Association (AUA) San Diego, California	05/2013
The Impact of InhibiZone on Artificial Urinary Sphincter Infection Rate American Urological Association (AUA) San Diego, California	05/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse American Urological Association (AUA) San Diego, California	05/2013
Long Term Risk for Repeat Anti-Incontinence Surgery following Urethrolysis: A Review of 100 Patients American Urological Association (AUA) San Diego, California	05/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 3rd International Meeting "Challenges in Endourology & Functional Urology" Paris, France	06/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Device Explantation for Erosion and/or Infection South Central Section of the AUA Chicago, Illinois	09/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013

Long-term impact of artificial urinary sphincter reimplantation following prior device explantation for erosion and/or infection 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long-Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Risk Factors for Intraoperative Conversion During Robotic Sacrocolpopexy Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Results of artificial urinary sphincter reimplantation following previous erosion and/or infection 29th Annual Congress of the European Association of Urology Stockholm, Sweden	04/2014
Autologous Transobturator Mid-Urethral Sling Placement: A Novel Outpatient Procedure for Female Stress Urinary Incontinence (Video Presentation) American Urological Association (AUA) Orlando, Florida	05/2014
Surgical Management of Female Benign Urethral Stricture Disease: A Ten Year Experience American Urological Association (AUA) Orlando, Florida	05/2014
Urethral Management at the Time of Artificial Urinary Sphincter Erosion, Is Urethral Catheterization Alone Enough? North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Autologous Transobturator Mid-Urethral Sling Placement for Female Stress Urinary Incontinence (Video Presentation) North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014

Poster

Robot-Assisted Laparoscopic Sacrocolpopexy for Treatment of High Grade Vaginal Vault Prolapse: Surgical Technique and Initial Experience 29th Congress of the Societe Internationale d'Urologie Paris, France	09/2007
Robot Sacrocolpopexy: A Review of the Learning Curve in Fifty Casesl 4th World Congress on Controversies in Urology (CURy) Paris, France	01/2011
Impact of Radiotherapy on Surgical Repair and Outcomes in Patients with Rectourethral Fistula. 67th Annual Meeting of the Canadian Urological Association Alberta, Canada	06/2012

Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection
American Urological Association (AUA)
Orlando, Florida — 05/2014

Factors Associated with Intraoperative Conversion During Robotic Sacrocolpopexy
North Central Section of the American Urological Association (AUA)
Chicago, Illinois — 09/2014

Regional

Invited

Rectocele
Office of Women's Health brown bag
Rochester, Minnesota — 10/2004

Incontinence and Other Urological Issues
Radio Broadcast, Hosted by Dr. Thomas Shives
HealthLine - KROC Radio
Rochester, Minnesota — 08/2007

A Practical Approach to Treating Incontinence
Clinical Reviews, Rochester Civic Center
Rochester, Minnesota — 10/2008

A Practical Approach to Treating Incontinence
Clinical Reviews, Rochester Civic Center
Rochester, Minnesota — 11/2008

Incontinence and Other Urological Issues
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota — 03/2010

Urinary Incontinence
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota — 03/2011

Incontinence: Causes and Treatments
Prostate Cancer Support Group
Rochester, Minnesota — 02/2013

Urinary Incontinence
Radio Broadcast, Hosted by Dr. Thomas Shives
Medical Edge Weekend - KROC Radio
Rochester, Minnesota — 05/2014

Oral

Paratesticular Angiomyofibroblastoma
North Central Section, American Urological Association
Minneapolis, Minnesota — 09/1995

Does the Degree of Preoperative Elevation PSA Exclude a Patient for Consideration for Radical Retropubic Prostatectomy?
North Central Section, American Urological Association
Tucson, Arizona — 10/1996

Does Reoperation of an Artificial Sphincter Place the Patient at an Increased Risk for Subsequent Reoperation North Central Section, American Urological Association Amelia Island, Florida	10/1998
Is Fascia Lata Allograft Material Trustworthy for Pubovaginal Sling Repair North Central Section, American Urological Association Phoenix, Arizona	10/2000
Combined Stent and Artificial Urinary Sphincter for Management of Severe Recurrent Bladder Neck Contractures and Stress Incontinence after Prostatectomy: A Long-Term Evaluation. North Central Section, American Urological Association Phoenix, Arizona	10/2000
Does Nocturnal Deactivation of the Artificial Urinary Sphincter Lessen the Risk for Urethral Atrophy? North Central Section, American Urological Association Phoenix, Arizona	10/2000
Robotics Surgery for Vaginal Prolapse Controversies in Women's Health Symposium 2007 Nisswa, Minnesota	06/2007

Research Grants Awarded

Completed Grants

Federal

Co-Investigator	Selenium and Vitamin E Cancer Prevention Trial (SELECT). Funded by National Cancer Institute. (U10 CA 37429-SELECT)	01/2010 - 12/2010

Industry

Principal Investigator	Are There Histological and Tensile Strength Variations in Autologous, Allograft and SIS Pubovaginal Slings Over Time Using the Rabbit Model. Funded by Mentor Corporation. (MENTOR #5, 1A4575)	10/2002 - 09/2003
Co-Investigator	Single Looped Mechanical Urinary Sphincter: Determination of Required Urethral Constriction Forces to Provide Adequate Urinary Continence in the Canine Model. Funded by Dacomed, Inc. (Dacomed #1)	10/1995 - 12/1995
Co-Investigator	Clinical Investigation of the Safety and Performance of Timm Medical Technologies' Artificial Urinary Sphincter (TIMM-AUS). Funded by Timm Medical Technologies. (Timm # 1)	06/1999 - 02/2005
Co-Investigator	A Randomized, Double-Blind, Parallel-Group Study to Investigate the Effects of a Single Oral Dose of L-753099 Compared to Placebo and Tolerodine on Urodynamic Parameters in Healthy Male Volunteers. Funded by Merck & Co., Inc. (Merck 138)	07/1999 - 12/2003
Co-Investigator	The Safety, Local Tolerability, Pharmacokinetics, and Risk Benefit of Oxybutynin Transvaginal Rings (TVR) in Women with a History of Overactive Bladder. Funded by Advanced Biologics. (BIOLOGICS #1)	01/2001 - 12/2003

Co-Investigator	An Eight-Week, Double-Blind, Randomized, Parallel Group Design, Multicenter Study of FLOMAX Capsules, 0.4 mg Daily Vs. Placebo, in Female Patients w/ Lower Urinary Tract Symptoms (LUTS) w/ a Significant Component of Voiding Symptoms. Funded by Boehringer Ingelheim. (BOEHRINGER #34)	06/2001 - 07/2003
Co-Investigator	Veritas Collagen Matrix Urological Sling Postmarketing Clinical Study Protocol. Funded by Bio-Vascular, Inc. (BIOVASCULAR #1)	10/2001 - 09/2003

Mayo Clinic

Principal Investigator	Transurethral Enzymatic Ablation of the Prostate (TEAP); Short-term Concentration Study. Funded by Department Discretionary Funds. (Immuno 2)	09/1995 - 12/2003

Bibliography

Peer-reviewed Articles

1. Gleason PE, **Elliott DS** , Zimmerman D, Smithson WA, Kramer SA. Metastatic testicular choriocarcinoma and secondary hyperthyroidism: case report and review of the literature. J Urol. 1994 Apr; 151(4):1063-4. PMID:8126794.

2. **Elliott DS** , Blute ML, Patterson DE, Bergstralh EJ, Segura JW. Long-term follow-up of endoscopically treated upper urinary tract transitional cell carcinoma. Urology. 1996 Jun; 47(6):819-25. PMID:8677570. DOI:10.1016/S0090-4295(96)00043-X.

3. **Elliott DS** , Barrett DM. Long-term followup and evaluation of primary realignment of posterior urethral disruptions. J Urol. 1997 Mar; 157(3):814-6. PMID:9072573.

4. **Elliott DS** , Barrett DM. The artificial urinary sphincter in the female: indications for use, surgical approach and results. Int Urogynecol J Pelvic Floor Dysfunct. 1998; 9(6):409-15. PMID:9891964.

5. **Elliott DS** , Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol. 1998 Apr; 159(4):1206-8. PMID:9507835.

6. Brown JA, **Elliott DS** , Barrett DM. Postprostatectomy urinary incontinence: a comparison of the cost of conservative versus surgical management. Urology. 1998 May; 51(5):715-20. PMID:9610584.

7. **Elliott DS** , Barrett DM. The artificial genitourinary sphincter. Digital Urology Journal. 1998 Jul.

8. **Elliott DS** , Timm GW, Barrett DM. An implantable mechanical urinary sphincter: a new nonhydraulic design concept. Urology. 1998 Dec; 52(6):1151-4. PMID:9836575.

9. **Elliott DS** , Boone TB. Urethral devices for managing stress urinary incontinence. Journal of Endourology. 2000 Feb; 14(1):79-83. PMID:10735576.

10. **Elliott DS** , Barrett DM. Artificial urinary sphincter implantation using a bulbous urethral cuff: perioperative care. Urol Nurs. 2000 Apr; 20(2):89-90, 95-8. PMID:11998129.

11. Frank I, **Elliott DS** , Barrett DM. Success of de novo reimplantation of the artificial genitourinary sphincter. J Urol. 2000 Jun; 163(6):1702-3. PMID:10799164.

12. Petrou SP, **Elliott DS** , Barrett DM. Artificial urethral sphincter for incontinence. Urology. 2000 Sep 1; 56(3):353-9. PMID:10962293.

13. **Elliott DS** , Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology. 2000 Nov 1; 56(5):772-6. PMID:11068297.

14. **Elliott DS** , Boone TB. Recent advances in the management of the neurogenic bladder. Urology. 2000 Dec 4; 56(6 Suppl 1):76-81. PMID:11114567.

15. **Elliott DS** , Boone TB. Combined stent and artificial urinary sphincter for management of severe recurrent bladder neck contracture and stress incontinence after prostatectomy: a long-term evaluation. J Urol. 2001 Feb; 165(2):413-5. PMID:11176385. DOI:10.1097/00005392-200102000-00014.

16. **Elliott DS** , Mutchnik S, Boone TB. The "bends" and neurogenic bladder dysfunction. Urology. 2001 Feb; 57(2):365. PMID:11182361.

17. Kim IY, **Elliott DS** , Husmann DA, Boone TB. An unusual presenting symptom of sarcoidosis: neurogenic bladder dysfunction. J Urol. 2001 Mar; 165(3):903-4. PMID:11176503.

18. Petrou SP, **Elliott DS** . Artificial urethral sphincter for incontinence in adults. Drugs Today (Barc) 2001 Apr; 37(4):237-244. PMID:12768224.

19. **Elliott DS** , Barrett DM, Gohma M, Boone TB. Does nocturnal deactivation of the artificial urinary sphincter lessen the risk of urethral atrophy? Urology. 2001 Jun; 57(6):1051-4. PMID:11377302.

20. **Elliott DS** , Segura JW, Lightner D, Patterson DE, Blute ML. Is nephroureterectomy necessary in all cases of upper tract transitional cell carcinoma? Long-term results of conservative endourologic management of upper tract transitional cell carcinoma in individuals with a normal contralateral kidney. Urology. 2001 Aug; 58(2):174-8. PMID:11489692.

21. Lightner DJ, **Elliott D** , Gillett M. Surgeon's corner. Transvaginal culdoplasty for posthysterectomy vaginal vault prolapse. Contemp Urol. 2003 Sep; 15(9):15-22.

22. DiMarco DS, **Elliott DS** . Tandem cuff artificial urinary sphincter as a salvage procedure following failed primary sphincter placement for the treatment of post-prostatectomy incontinence. J Urol. 2003 Oct; 170(4 Part 1):1252-4. PMID:14501735.

23. **Elliott DS** , Barrett DM. Current indications for the use of the artificial genitourinary sphincter and management of its complications. The Scientific World Journal. 2004; 4(S1):114-27.

24. Di Marco DS, Chow GK, Gettman MT, **Elliott DS** . Robotic-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse. Urology. 2004 Feb; 63(2):373-6. PMID:14972496. DOI:10.1016/j.urology.2003.09.033.

25. Dora CD, Dimarco DS, Zobitz ME, **Elliott DS** . Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol. 2004 May; 171(5):1970-3. PMID:15076323. DOI:10.1097/01.ju.0000121377.61788.ad.

26. **Elliott DS** , Frank I, DiMarco DS, Chow GK. Gynecologic use of robotically assisted laparoscopy: sacrocolpopexy for the treatment of high-grade vaginal vault prolapse. Am J Surg. 2004 Oct; 188(4A Suppl S):52S-56S. PMID:15476652.

27. Krambeck AE, Dora CD, Sebo TJ, Rohlinger AL, DiMarco DS, **Elliott DS** . Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. Urology. 2006 May; 67(5):1105-10. PMID:16698388. DOI:10.1016/j.urology.2005.11.036.

28. **Elliott DS** , Chow GK, Gettman M. Current status of robotics in female urology and gynecology. World J Urol. 2006 Jun; 24(2):188-92. Epub 2006 Mar 24. PMID:16557388. DOI:10.1007/s00345-006-0071-5.

29. Petrou SP, Thiel DD, **Elliot DS** , Broderick GA, Wehle MJ, Young PR. Does indigo carmine prevent early artificial urinary sphincter cuff erosion? Can J Urol. 2006 Aug; 13(4):3195-8. PMID:16952328.

30. **Elliott DS** , Krambeck AE, Chow GK. Long-term results of robotic assisted laparoscopic sacrocolpopexy for the treatment of high grade vaginal vault prolapse. J Urol. 2006 Aug; 176(2):655-9.

31. Routh JC, Crimmins CR, Leibovich BC, **Elliott DS** . Impact of Parkinson's disease on continence after radical prostatectomy. Urology. 2006 Sep; 68(3):575-7. Epub 2006 Sep 18. PMID:16979722. DOI:10.1016/j.urology.2006.03.025.

32. **Elliott DS** , Chow GK. [Management of vaginal vault prolapse repair with robotically-assisted laparoscopic sacrocolpopexy]. Ann Urol (Paris) 2007 Feb; 41(1):31-6. PMID:17338498.

33. Magera JS Jr, **Elliott DS** . Tandem transcorporal artificial urinary sphincter cuff salvage technique: surgical description and results. J Urol. 2007 Mar; 177(3):1015-9; discussion 1019-20. PMID:17296400. DOI:10.1016/j.juro.2006.10.052.

34. Krambeck AE, Thompson RH, Lohse CM, Patterson DE, Segura JW, Zincke H, **Elliott DS** , Blute ML. Endoscopic management of upper tract urothelial carcinoma in patients with a history of bladder urothelial carcinoma. J Urol. 2007 May; 177(5):1721-6. PMID:17437796.

35. Krambeck AE, Thompson RH, Lohse CM, Patterson DE, **Elliott DS** , Blute ML. Imperative indications for conservative management of upper tract transitional cell carcinoma. J Urol. 2007 Sep; 178(3 Pt 1):792-6; discussion 796-7 Epub 2007 Jul 16. PMID:17632132. DOI:10.1016/j.juro.2007.05.056.

36. Magera JS Jr, Inman BA, **Elliott DS** . Does preoperative topical antimicrobial scrub reduce positive surgical site culture rates in men undergoing artificial urinary sphincter placement? J Urol. 2007 Oct; 178(4 Pt 1):1328-32; discussion 1332. Epub 2007 Aug 14. PMID:17698144. DOI:10.1016/j.juro.2007.05.146.

37. **Elliott DS** , Frank I, Chow GK. Robotics and laparoscopy for vaginal prolapse and incontinence. Current Bladder Dysfunction Reports. 2007 Dec; 2(4):214-8.

38. Thompson RH, Krambeck AE, Lohse CM, **Elliott DS** , Patterson DE, Blute ML. Endoscopic management of upper tract transitional cell carcinoma in patients with normal contralateral kidneys. Urology. 2008 Apr; 71(4):713-7. Epub 2008 Feb 11. PMID:18267338. DOI:10.1016/j.urology.2007.11.018.

39. Thompson RH, Krambeck AE, Lohse CM, **Elliott DS** , Patterson DE, Blute ML. Elective endoscopic management of transitional cell carcinoma first diagnosed in the upper urinary tract. BJU Int. 2008 Nov; 102(9):1107-10. Epub 2008 Jun 03. PMID:18522631. DOI:10.1111/j.1464-410X.2008.07766.x.

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